REMARKS

Claims 67-73, and 75 are pending in this application. Claims 67, 70, and 73 have been amended herein. Claim 74 has been canceled by this amendment. New claims 76-87 have been added herein. Reconsideration and allowance of the present application based on the following remarks is respectfully requested.

35 U.S.C. §112 Rejections

The Office Action rejected claims 73 and 75 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 73 has been amended herein to incorporate the step of dependent claim 74. Claim 75, which is dependent from amended claim 73, now also incorporates this step. Applicants submit that, as amended, claim 73 and dependent claim 75 are not indefinite and withdrawal of the rejection is respectfully requested. Applicants thank the Examiner for his helpful suggestion with regard to this rejection.

35 U.S.C. §103 Rejections

1. Rejection over Pethig in view of Lipshutz

The Office Action rejected claims 67-69 as being unpatentable over Pethig et al., (Tibtech, 1997, vol. 15, pages 426-432) (hereafter, Pethig) in view of Lipshutz et al., (U.S. Patent No. 6,043,080) (hereafter Lipshutz). Applicants respectfully traverse the rejection for at least the reasons which follow.

Applicants' claimed invention, as amended is a method of obtaining nucleic acid from a sample of heterogenous biological elements, the method comprising:

providing a sample comprising heterogenous biological elements;

physically isolating an individual biological element or a subset of the biological elements of the sample within a microfluidic chamber wherein the microfluidic chamber is a cell pen, a cell cage, or a gated cross-flow injection structure;

lysing the individual biological element or the subset of biological elements;

purifying nucleic acid from the individual biological entity or the subset of biological entities; and

amplifying at least a portion of the purified nucleic acid. Applicants claimed invention provides for an integrated method of directly obtaining and amplifying nucleic acid from an individual biological element or a subset of biological elements isolated within a microfluidic chamber. This is accomplished by utilizing microfluidic platforms such as those described in Applicants' specification that provide for the efficient and precise isolation of a biological element(s) within a microfluidic chamber.

Pethig describes dielectrophoresis as a technique for cell sorting. The Office Action relies upon Pethig for the description of a bacterial sorting technique. Lipshutz is relied upon by the Office Action for describing a method of using a microfluidic device which comprises multiple chambers which conduct different types of assays.

Applicants' claim 67, as amended, recites the isolation of an individual biological element or a subset of the biological elements of the sample within a microfluidic chamber wherein the microfluidic chamber is a cell pen, a cell cage, or a gated cross-flow injection structure. Support for this amendment is found with Applicants' specification at paragraphs 0180, 0184, and 0245, among other places. The use of the claimed method allows for very precise and low volume isolation, coupled to lysis, purification, and amplification steps. New claims 76-79 describe further features of Applicants claimed method including the introduction of lysing chemical through a cross-flow injection structure (claim 76), isolation of the microfluidic chamber through the activation of a deflectable membrane (claim 77), activation of the deflectable membrane by a control line (claim 78), and performance of lysis in a rotary mixer (claim 79). Support for the new claims is found within Applicants' specification including, for example, paragraph 0251, Fig. 29A, paragraphs 0133-0134, and 0256. Whatever else Pethig and Lipshutz may disclose, they do not disclose or suggest methods of obtaining nucleic acid involving such techniques. Accordingly, claim 67 is neither anticipated nor made obvious by Pethig or Lipshutz either alone or in combination. Claims 68, 69, and new claims 76-79 which depend from claim 67 are likewise neither anticipated nor made obvious by the cited art. Withdrawal of this rejection is respectfully requested.

2. Rejection over Burlage in view of Pethig and Lipshutz

The Office Action rejected claims 70, 71, and 73-75 as being unpatentable over Burlage (US 2003/0099928) (hereafter Burlage) in view of Pethig and Lipshutz. Applicants respectfully traverse the rejection for at least the reasons which follow.

Applicants' claimed invention, as amended, are methods of characterizing phylogenic, gene, and functional diversity exhibited by a specific environment and methods of obtaining genetic information regarding an individual biological element of a complex environmental sample.. The reasons sent forth above with regard to the rejection of claim 67 over Pethig in view of Lipshutz are equally applicable to Burlage. None of the references disclose or suggest Applicants' claimed methods of characterizing phylogenic, gene, and functional diversity exhibited by a specific environment. New claims 80-83 which depend from claim 70 and claims 84-87 which depend from claim 73 describe further features of Applicants claimed method including the introduction of lysing chemical through a cross-flow injection structure (claims 80 and 84), isolation of the microfluidic chamber through the activation of a deflectable membrane (claims 81 and 85), activation of the deflectable membrane by a control line (claims 82 and 86), and performance of lysis in a rotary mixer (claims 83 and 87). Whatever else Burlage, Pethig and Lipshutz may disclose, they do not disclose or suggest methods of obtaining nucleic acid involving such techniques. Accordingly, claims 70, 71, and 73-75 are neither anticipated nor made obvious by Burlage, Pethig or Lipshutz either alone or in combination. New claims 80-87 which depend from claim 70 or claim 73 are likewise neither anticipated nor made obvious by the cited art. Withdrawal of this rejection is respectfully requested.

3. Rejection over Burlage in view of Fu and Lipshutz

The Office Action rejected claims 70-75 as being unpatentable over Burlage in view of Fu et al., (Nature Biotechnology, 1999, vol.17, pages 1109-1111) (hereafter Fu) and Lipshutz. This rejection is respectfully traversed. Whatever else Fu may disclose, it does not remedy the deficiencies of Burlage and Lipshutz, as described above. As such, it is submitted that the claims are patentable over the cited art, and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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